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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,067	10/26/2001	Roger Coleman	PF-0069-1 CON	7844

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EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	13

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/033,067	COLEMAN ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9,10,12-16,28,29,46,47 and 57-59* is/are pending in the application.

4a) Of the above claim(s) *1,14-16,28,29,47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,9,10,12,13,46, 57-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 2, 11, 17-27, 30-45, 48-56 have been canceled previously and claims 8 and 11 have been canceled in Paper No. 9, 1/21/03. Claims 4-7, 9-10, 12-13, 46, 57, amended claim 3 (Paper No. 12, 6/20/03) and claims 58-59 are under consideration.

2. Receipt of applicant's arguments and amendments filed in Paper No. 12 (6/20/03) is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 12, 6/20/03:

(i) Applicant's arguments with respect to the 35 U.S.C. § 112, second paragraph rejection over claims 3-7, 9-10, 46, 57 have been considered but are moot in view of the new ground of rejection; and

(ii) the rejection of claims 3, 6-7 and 9 under 35 U.S.C. § 102(b) as being anticipated by Rollins et al. (U.S. Pat No. 5,278,287).

4. Applicant's arguments filed in Paper No. 12 (6/20/03) have been fully considered but were persuasive in part. The issues remaining and new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101/112, first paragraph

6. Claims 3-7, 9-10, 12-13, 46, 57-59 are rejected under 35 U.S.C. § 101.

This rejection is maintained for reasons of record set forth at pages 4-7 of the previous Office action (Paper No. 11, 3/21/03).

Applicants argue that the invention at issue is a polynucleotide expressed in various tissues which polynucleotide encodes a polypeptide, which "may" activate and cause the proliferation of monocytes, macrophages, basophils, eosinophils, T-lymphocytes and fibroblasts. Furthermore, Applicants argue that the claimed invention has beneficial uses in toxicology testing, drug development and diagnosis of disease. Appellants summarize case law on the utility requirement at pages 9-10 of their response. The essential disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility, as will be explained more fully below.

Applicants argue at pages 10-17 of the response that the claimed polynucleotides are useful as tools for toxicology testing, drug discovery, and the diagnosis of disease and that these uses are "well-established". It is noted that toxicology testing and drug discovery are not specifically recited in the specification as originally filed. Each of these uses will be addressed individually, because the facts and issues directed to each use are distinct and separable. First, Applicants argue that toxicology testing is a well-established utility and conclude that the claimed polynucleotides could be used in this manner and that the claimed invention possesses utility. However, for a utility to be "well-established" it must be specific, substantial and credible. In this case, all nucleic acids and genes are in some combination useful in toxicology testing. However, the particulars of toxicology testing with SEQ ID NO:2 are not disclosed in the instant specification. Neither the toxic substances nor the susceptible organ systems are identified. Therefore, this is a utility, which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA, but is only potential with respect to SEQ ID NO:2. Because of this, such a utility is not specific and does not constitute

a "well-established" utility. Further, because any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. Moreover, use of the claimed polynucleotide in an array for toxicology screening is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array. Again, this is a utility, which would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of Applicants' individual polynucleotide is affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed polynucleotide has no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information regarding this nucleic acid could be put.

Applicants argue that expression profiling is one uses of the claimed polynucleotide. Transcript imaging is a method for quantifying the relative expression levels of a large number of gene transcripts within a biological sample. In this manner a gene expression profile is generated. Such a profile is independent of the function of the genes or gene products. In the instant case, the claimed polynucleotides can be used as one of many targets on a microarray to generate a transcript image. A transcript image generated from lung tumor tissue can be compared, for example, with that from lung tumor tissue treated with a potential compound in order to evaluate the efficacy of the compound.

However, Applicants are incorrect in asserting that the efficacy (ability of producing a desired effect) of a compound could be evaluated from the result of a transcript image because there is no way to assess the meaning of any individual hit obtained from this procedure. The first requirement is that one must know the biological significance of the polynucleotide(s) that is(are) being evaluated. Without this information, the results of the transcript image are useless because one would not know if the polynucleotide expression should be increased or decreased or even what significance could be attributed to such changes in expression profiles. The specification alleges that the claimed polynucleotide encodes a protein which "may" activate and cause the proliferation of monocytes, macrophages, basophils, eosinophils, T-lymphocytes and fibroblasts. However, from the disclosure of the instant specification, one of ordinary skill in the art could not glean from the instant specification as filed and would not be able to use the information in the instant specification in a useful manner. There is no evidence to the contrary.

With regard to diagnosis of disease, Applicants argue that there is no requirement that each and every gene have an established correlation with a particular disease. However, in order for a polynucleotide to be useful, as asserted, for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. The presence of a polynucleotide in tissue that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some

expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Appellants state that the "claimed invention could be used, for example, in a toxicology test to determine whether a drug or toxin causes any change in the expression of growth factors". However, the specification does not disclose the significance of any test results, nor is there any evidence that the significance was known as of the filing date. If the expression of the claimed polynucleotide increases, is this a positive or negative outcome? Would this be a toxic response or not? The disclosure is insufficient to evaluate the results of the test in any meaningful manner.

Applicants further argue that the claimed polynucleotide could serve "as a marker of a toxic response, or alternatively, if levels of the claimed polynucleotide remain unchanged during a toxic response, as a control in toxicology testing". However, this use is speculative at best, as well as not being specific or substantial in that any polynucleotide may possess the property of being a marker for some toxic response. It would appear that Applicants are describing a "wish to know" type of utility, which is not a specific, substantial and credible utility. Applicants assert that knowledge of the specific functions of the encoded protein, i.e. the function or role of the protein in its natural state, is not required for use of the polynucleotide in diagnosis of disease. The validity of this argument requires some correlation to a disease. On this record, such a correlation is absent.

Applicants argue that a utility may be specified even if it applies to a broad class of inventions. The proposition is not sufficient to establish utility for each member of the class. Specific utility must be shown or be evident for each member of the class. None of the utilities identified by Applicants, i.e. toxicology testing, drug discovery, disease diagnosis, have been demonstrated to be specific to SEQ ID NO:2. One of ordinary skill in the art must understand how to achieve an immediate and practical benefit from the claimed species based on the knowledge of the class. However, no practical benefit has been shown for the use of SEQ ID NO:2.

Applicants argue on page 17-18 that practical utility of an invention may be derived from belonging to a broad class of inventions. The requirement in any particular case, however, is that practical utility can be inferred if each and every member of the broad class possesses a common utility. In the instant case, hJE-2/MCP-2 and MCP-3 do not have the

same chemotactic activity of the MCPP polypeptide asserted in the instant claims. MCP-2 and MCP-3 are only chemotactic for monocytes. Therefore, Applicants expansion of this concept to different "classes" of proteins with the assertion that each "class" possesses a specific, substantial and credible or well-established utility is not persuasive. To put it concretely, one of ordinary skill in the art would not be able to use the claimed invention without knowing in which way and on what target cells the claimed invention would operate as a chemotactic agent.

At page 28 argue that the rejection is made based on a scientifically incorrect and legally unsupportable assertion that the identification of the family or families of proteins to which the claimed invention belongs, without more, does not satisfy the utility requirement". The rejection is based on the failure to disclose sufficient properties of the protein and/or polynucleotide and the MCPP protein encoded thereby to support an inference of utility. The C-C chemokine family to which the polypeptide encoded by the claimed polynucleotide belongs is a family in which the members have divergent functions based on which tissues the protein is expressed or administered to and on what cells the protein is chemotactic. Assignment to this family does not support an inference of utility because the members are not known to share a common utility. There are some protein families for which assignment of a new protein in that family would convey a specific, substantial and credible utility to that protein. For example, some families of enzymes such as proteases, ligases, telomerases, etc. share activities due to the particular specific biochemical characteristics of the members of the protein family such as non-specific substrate requirements, that are reasonably imputed to isolated compositions of any member of the family.

For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Moreover, the references of Rockett et al, Lashkari et al., Nuwaysir et al., Bork and Steiner et al. do not exemplify the state of the art at the time of the instant invention because they were published 2-3 years after the filing date of the instant application and they rely on information that was not available at the time of the instant invention. See *In re Wright*, 27 USPQ 1510, 1514 (Fed. Cir. 1993) (developments occurring after the filing date are of no consequence regarding what one skilled in the art believed as of the filing date).

Appellants assert that there exists a market "for databases containing all expressed genes". However, this assertion fails to address the utility of the individually claimed polynucleotide of the invention of the instant application. The claims are to isolated chemical compositions, not to descriptive information included in a database. Therefore, for reasons set forth above,

Appellants arguments and exhibits have been fully and carefully considered, but are not considered sufficient to rebut the prima facie case of lack of utility.

The Declaration by Dr. Tod Bedilion under 37 C.F.R. 1.132 filed in Paper No. 12, 6/20/2003, is insufficient to overcome the rejection of claims 3-7, 9-10, 12-13, 46, 57-59 based upon a lack of specific and substantial utility as set forth in the last Office action because it merely presents Applicants' arguments in declaratory form, such arguments having already been answered o the record. Furthermore, the art submitted has been considered but does not pertain to the particular polynucleotide claimed.

Claims 3-7, 9-10, 12-13, 46, 57-59 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation. This rejection is maintained for reasons set forth above in the statement of the grounds of rejection under 35 U.S.C. §101.

Claim Rejections - 35 USC § 112, first paragraph-written description

7a. Claims 3, 6-7, 9, 12-13, 46, 59 are rejected under 35 U.S.C. § 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 9-11 of the previous Office action (Paper No. 11, 3/21/03).

The written description in this case only sets forth a polynucleotide of SEQ ID NO:2 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claims drawn to "a naturally occurring amino acid sequence at

least 90% identical to the amino acid sequence of SEQ ID NO:1" as recited for example in claim 3.

Applicants argue that the genus of the claimed invention is sufficiently described in the specification to convey to one of ordinary skill in the art that Applicant had possession of the claimed genus of polynucleotide sequences encoding a polypeptide. Furthermore, Applicant argues that the one of ordinary skill in the art would recognize variants having "a polynucleotide sequence at least 90% identical to SEQ ID NO:2". However, contrary to Applicants arguments, the issue here is that Applicants have not provided a written description for "a polynucleotide encoding a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1" as recited for example in claim 3. There is a considerable difference between what Applicants are arguing is being claimed and what is explicitly being claimed.

The instant specification clearly describes the claimed polynucleotide sequence as set forth in SEQ ID NO: 2, and that this complete nucleotide sequences would convey to one of skill in the art that Applicants were in possession of the polynucleotide sequence. However, contrary to Applicant's arguments, the claims encompass a genus of polynucleotides variants encoding proteins having one or more amino acid deletions, insertions and/or additions made to SEQ ID NO: 1. The specification and claims do not indicate what are the distinguishing attributes shared by the members of the genus for which the common portion is responsible for functional activity. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted.

Applicant argues that while the genus encompasses a large number of embodiments, it is not unpredictably variant and that variance is limited to that tolerated by the genetic variance in coding sequence for a particular amino acid in the disclosed sequence. However, contrary to Applicant's arguments, although the specification states that these types of changes are routinely done in the art the specification and claims do not provide a written description as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural and functional attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, polynucleotides encoding a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1 alone, as recited for example in claim 3, are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus.

7b. Claims 13 and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13, 59 recite "comprising at least 60 contiguous nucleotides" and encompasses a genus of nucleic acid molecules comprise only portions of the full-length sequence of SEQ

ID NO:2 as well as variants having one or more nucleotide deletions, insertions and/or additions made to SEQ ID NO: 2. The specification and claims do not indicate what are the distinguishing attributes shared by the members of the genus for which the common portion is responsible for functional activity. The specification and claims do not place any limit on the number of nucleotides that may be added to the portions since the claim is not limited to the full-length SEQ ID NO:2. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide a written description as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural and functional attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, nucleic acid molecules comprising at least 60 contiguous nucleotides of SEQ ID NO:2 alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus of polynucleotides.

Claim Rejections - 35 USC § 112, first paragraph-scope of enablement

8. Claims 3, 6-7, 9, 12-13, 46, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 1, does not reasonably provide

enablement for a "naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1".

This rejection is maintained for reasons of record set forth at pages 8-9 of the previous office action (Paper No. 11, 3/21/03)

Applicants argue that through the process of natural selection, nature will have determined the appropriate amino acid sequence. However, contrary to applicants arguments, no guidance is provided as to which of the myriad of polynucleotide species encoding polypeptide species encompassed by the claim will retain the characteristics of the desirable polypeptide.

PM 9/4/03

In the specification on page 4, lines 22-32, Applicants disclose that variants of MCPP include deletions, substitutions or additions of amino acids without abolishing activity. Therefore, the claimed genus of polynucleotides encoding MCPP polypeptides encompasses variants that share activity, however, the specification does not teach how to make a polynucleotide sequence encoding a polypeptide having an amino acid sequence less than SEQ ID NO:1, that would share those activities. Applicants are not claiming polynucleotide sequences that are "probes" but polynucleotide sequences that encode MCPP proteins. The specification only enables polynucleotides encoding MCPP proteins of amino acid sequence set forth in SEQ ID NO:1, and is not enabled for a polynucleotide encoding a polypeptide having an amino acid sequence anything less than what is disclosed in SEQ ID NO:1, the claimed polypeptides having specific characteristics.

The issue in the instant case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

Furthermore, the recitation of "at least 60 contiguous nucleotides..." in claim 13, is not a sufficient structural limitation and broadly encompasses any polynucleotide comprising at least

60 contiguous nucleotides as recited in the claim. Because of the presence of the term "comprising" in claim 13, the claim encompasses a polynucleotide comprising any 60 contiguous nucleotides from SEQ ID NO:2, and therefore the claim encompasses embodiments encompassing any other 800 nucleotides or more in addition to these 60 contiguous nucleotides. The number of polynucleotide embodiments in this case are over 5×10^{200}.

Furthermore, the instant specification does not provide the guidance needed to use these polynucleotides as claimed. Even if Applicants recited a functional limitation for the MCPP polypeptide in the instant claims, Applicants have not taught how to make the instant polynucleotides with the stretch of 60 contiguous nucleotides as recited in claim 13. The instant specification does not teach which polynucleotides encoding polypeptides would predictably be associated with that function. There is no guidance in the specification for how to make and use polynucleotides encoding proteins having the amino acid sequences anything less than that disclosed in SEQ ID NO:1.

Applicants arguments on page 5 that the standard is that routine experimentation is required to identify the numerous embodiments is a position that has been routinely dismissed by the courts, as shown by the CAFC decision in Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein and recombinant DNA issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of

trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims.

Further, In re Wands determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally-occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a polynucleotide encoding a polypeptide comprising at least 60 contiguous amino acids of SEQ ID NO:2. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the three disclosed naturally-occurring proteins, which are required for functional and structural integrity of those proteins. It is this additional characterization of the three disclosed proteins that is required in order to obtain the structural data needed to permit one to produce the claimed polynucleotide encoding a protein which meets the structural requirements of the instant claims that constitutes undue experimentation.

Claim rejections-35 USC § 112, second paragraph

9. Claims 3, 6-7, 9, 12-13, 46, 58-59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite because it recites "chemotactic activity". However, it is unclear for which type of cells the polypeptide encoded by the claimed polynucleotide, is chemotactic.

Claims 3, 12-13, are indefinite in the recitation of the term "naturally occurring". It is unclear whether this term imposes a required limitation on the claim, such that it only encompasses, for example, polynucleotides amplified from human cDNA, or only sequences produced by digestion with restriction enzymes of DNA isolated from tissue which contains polynucleotides encoding the polypeptide, or if the claim encompasses all polynucleotide sequences that encode the polypeptide. Therefore, the metes and bounds of the claim are unclear.

Claim 58, sub-part (a) is incorrect because it recites "a polynucleotide comprising the amino acid sequence of SEQ ID NO:2" rather than "a polynucleotide comprising the nucleotide sequence of SEQ ID NO:2".

Claims 6-7, 9, 46, 59 are rejected insofar as they are dependent on the above rejected claims of their limitations.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 28, 2003